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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,807	03/04/2005	Haruki Mizukami	SHM-101-PCT	5414

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,807	MIZUKAMI, HARUKI	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment dated 16 August 2007 has been received. Claims 2-3 and 9-16 have been canceled. Claims 17-21 have been added.

2. Claims 1, 3-8 and 17-21 are pending.

Claim Rejections - 35 USC § 112

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague because it does not further limit claim 1 from which it depends. The labeled reagents are not part of the device since it is added at the time of the assay.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossom et al (US 4,623,461).

The instant invention is a device comprising a contact portion, an unbound label capture portion and a detection portion. The recitation of the specific reaction product is not given patentable weight since the reagents of the device are not specifically limited to these analytes.

Hossom discloses a device comprising a liquid input means with a filter means for receiving the liquid from the liquid input means (i.e. contact portion), a peripheral zone to capture or receive unreacted liquid (i.e. unbound label capture portion), and a reaction zone where immunological binding takes place causing a color change or other reaction reading signals that can be viewed or read through a viewing port. See column 2, line 66 through column 3, line 37. Hossom teaches prespotting the reaction zone with binding reagents specific for the analyte. (Column 5, lines 25-31.)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 4-8 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al (US 5,141,850) in view of Fitzpatrick et al (US 5,451,504).

Cole discloses a device and method comprising a water-dispersible labeled component that comprises the coupling product of a first immunologically reaction substance and a detectable species; providing a water-dispersible capturable component that comprises the coupling product of a capturable species and a second immunologically reactive substance; providing a capturable component that is localized at a detection zone in a porous carrier material and which comprises a capturing substance capable of interaction with a reaction product containing the capturable species to thereby capture and collect the product at the detection zone. See column 2, lines 24-62. Cole discloses that the labeled component is initially a dry, reconstitutable, water-dispersible and diffusible and is reconstituted by the sample liquid. See column 2, line 63 through column 3, line 2.

Cole differs from the instant invention in failing to teach a zone to capture unbound label products.

Fitzpatrick, however, discloses a device similar to those of Cole. Fitzpatrick further teaches the capture of unbound labeled reagents. See column 1, line 57-68.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Cole to include a trap zone to capture unbound labeled reagents such as taught by Fitzpatrick because such modification would provide the advantage of a device that yields a detectable results in the case of a negative test leading to more accuracy in assay interpretation.

A skilled artisan would have had a reasonable expectation of success in assembling the device of Cole as modified by Fitzpatrick in a detection set, i.e. kit, such as taught by Cole because kits provide the advantages of economy and convenience and are well-known in the art.

8. Claims 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Fitzpatrick as applied to claim 1 above, and further in view of Durst et al (US 5,789,154).

See the discussion of Cole and Fitzpatrick above. These references differ from the instant invention in failing to teach the detection of dioxin and PCBs.

Durst, however, teaches that small analytes such as dioxin and PCBs are easily measurable using conventional techniques. See claim 13.

Therefore, it would have been obvious to one of ordinary skill the art at the time the invention was made to use the device of Cole as modified by Fitzpatrick to measure analytes such those taught by Durst because Cole teaches that their device is appropriate for the detection of a wide variety of analytes with the appropriate selection of reagents.

Response to Arguments

9. Applicant's arguments with respect to claims 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 10/24/07